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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,382	06/15/2001	Wan S. Lee	1408.017	8310

23405 7590 07/01/2004

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,382	LEE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE under 1.114, filed 03/12/2004, and amendment, filed 05/07/2004.

Claims 16 and 17 have been canceled and claim 18 has been added. Claims 1-15 and 18 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/12/2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "non-aqueous solvent" and "acrylic backbone" were not described in the specification as originally filed. On page 9, lines 8-12, applicant disclosed the solvents that included water, ethanol, isopropanol, propylene glycol, glycerin, PEG, and all are aqueous solvent. Nowhere in the specification where acrylic backbone is supported.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,779,632 ('632).

US '632 disclosed a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed method for preparing a drug delivery device using the general method of mixing a solution of the drug and the adhesive, and coating the resulting adhesive composition on a backing (col.32, lines 17-26).

The limitations of claims 1, 2, and 18 are met by US '632 reference.

6. Claims 1, 4, 5, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,150,459 ('459).

US '459 discloses a polymer composition suitable for controlled release drug delivery devices and wound healing devices, said composition comprises acrylic backbone and poly(ethylene oxide) side chain (abstract; col.3, lines 52-54, 61-64; col.8, lines 56-67; col.9, lines 10-120; col.16, lines 45-49). The preferred molecular weight of the side-chain is above 200 and below 2000 and is present in amount of 20-60% of the polymer composition (col.3, lines 57-59; col.4, lines 14-23; col.9, lines 25-30; col.10, lines 53-61). The composition comprises active agent, and solvent and prepared by casting a solution comprising the polymer into a surface (col.12, lines 54-60).

The limitations of claims 1, 4, 5, and 18 are met by the reference.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '632 or US '459 in view of US 5,865,792 ('792).

The teachings of US '632 and US '459 are discussed above.

However, US '632 and US '459 do not teach the particular salts of the drugs as claimed in claims 6 and 13, the particular solvents of claims 7, or the amount of the drug, solvent and the penetration enhancer.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the drug, the solvent, and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymer composition comprising acrylic backbone and poly(ethylene oxide) side chain as disclosed by any of US '632 and US '459 and select one of the suitable solvents and drug salts disclosed by US '792 to be included in the composition, motivated by the teaching of US '792 that the drug salt and particularly hydrocortisone succinate is the preferred anti-inflammatory drug that

eliminates tissue irritation, with reasonable expectation of having polymer composition comprising acrylic backbone and poly(ethylene oxide) side chain to deliver hydrocortisone succinate with success to the patient in need.

Response to Arguments

10. Applicant's arguments filed 02/24/2004 have been fully considered but they are not persuasive.

Applicants argue that Dietz discloses only polymer emulsions, while the present claims require non-aqueous solution. Ledger fails to supply the deficiency of US '632 reference, as it merely states that an adhesive may be used, without providing any details how to prepare it.

In response to the above applicants' arguments, the examiner position is that Dietz disclosed polyethylene oxide acrylate soluble in water, and that will form a solution (col.10, lines 31-35). The expression "comprising" of the claim language permits the presence of the oil phase, i.e. emulsion. Furthermore, the "no-aqueous" recitation lacks support from the specification, and applicants actually disclosed aqueous solvents, as stated above. Ledger's reference is relied upon for teaching the specific salts of drugs and other ingredients as solvents and enhancers. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '792 teaches that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. preparation of the adhesive) are not recited in the rejected claim(s), and the rejected claims are directed to composition not process of making. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In any event, the US '632 reference teaches the general method of preparing the composition in col.32, lines 17-23.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER